

## REMARKS

This is a supplemental amendment filed in response to the Examiner's Interview held at the U.S. Patent Office in Alexandria, VA on January 25, 2011.

### I. Brief Summary of Examiner's Interview

Applicants' representative pointed out that the changes in claim wording in the amendment filed on December 21, 2010 should correct the deficiencies that led to the rejection of claims under 35 U.S.C. § 112, second paragraph, because the term "salts" is no longer used in the claims. Furthermore formula I represents a single compound, trigonelline, and the claim wording has been changed to account for that fact.

Trigonelline is an amphoteric compound, which is sometimes called an inner salt. Accordingly the use of the term "salts" is confusing and the new and amended claims above do not include the term "salt".

However the compounds of formula II are in fact salts of trigonelline. When the cation  $Y^+$  is the hydronium ion ( $H^+$ ), the corresponding compounds of formula II can be considered the product of a reaction between an acid of form  $HX$ , such as HCl, and trigonelline.

Thus the new and amended claims above should not be found to suffer from the deficiencies of the previously pending claims that led to their rejection as indefinite.

During the interview applicants' representative argued that the claimed methods were amended by the changes in the amendment filed in December 2010 to exclude methods disclosed in Cannell that merely "protect" the hair by providing a coating of e.g. a vegetable extract containing trigonelline on the hair. Applicants' representative argued that Cannell should not be included in the prior art references combined to reject the claims filed in the amendment of December 2010 as obvious. The Examiner disagreed with this argument.

The applicants' representative also argued that the new claim 40, which was intended to be limited to embodiments of the applicants' method described in comparative examples 1 to 4 on

pages 10 and following in applicants' US specification, was not obvious from the combination of the two prior art references of record, Stuckler and Cannell, used to reject the claims as obvious. The Examiner stated that the new independent method claim 40 had formal deficiencies and should be canceled, because the embodiments of the method in the respective examples must be claimed individually and specifically because of the significant differences between them. Also the written description apparently was considered to lack a generic disclosure that would encompass the subject matter of examples 1 to 4. The Examiner suggested that several new independent method claims of comparatively limited scope should be filed, which are each limited to the specific methods described in examples 1 to 4.

The Examiner stated that claim 32 would still be rejected for obviousness based on a combination of the US Patents, Stuckler and Cannell. Stuckler does disclose and claim a shampoo containing trigonelline (claims 12 and 13) but also containing vitamins such as B6, nicotinic acid or acid amide and calcium pantothenate as required ingredients. All the claimed processes and compositions of Stuckler at least require the administration of vitamin B6 as well as trigonelline.

Applicants' representative suggested that a new independent method claim similar to claim 32 but which claimed applying a treatment agent that excluded other active ingredients of Stuckler, such as vitamin B6, amino acids and nicotinic acid, as well as trigonelline, would be distinguished from the combined prior art.

The Examiner indicated that prosecution would be advanced if the suggested new more limited independent method claims corresponding to the applicants' examples were filed in a supplemental amendment. She also agreed that it would be helpful to file a new more limited generic method claim similar to claim 32. Accordingly this supplemental amendment has been prepared with the above new and amended claims in response to the suggestion of the Examiner.

## **II. The New and Amended Claims**

New independent method claim 42 replaces canceled method claim 32. New independent method claim 42 is the same as claim 32, except that the treatment agent of step a of the new claim 42 is defined narrowly using "consisting of" wording that excludes the other active ingredients, vitamin B6, and the optional nicotinic acid

and calcium pantothenate, which are included in the topical treatment agents of Stuckler in contrast to the orally administered treatment agents.

New independent method claim 42 has the greatest scope of patent claim coverage of any of the above-pending method claims. The treatment agent applied to the hair in the method of new claim 42 is limited to an agent consisting of 0.2 to 30 wt. % of at least one of the compound of formula I and the compounds of formula II, at least one auxiliary agent (individual auxiliary agents are selected from page 7 and the examples on page 10 and following of applicants' originally filed US specification) and at least one pH adjusting agent (as defined in the paragraph bridging pages 7 and 8 of applicants' US specification). This new claim 42 is fully supported by the disclosures in applicants' written description and no new matter has been entered.

The amount range limitation for the active ingredient in claim 42 is based on the range of 0.0005 to 30.0 wt. % for the active ingredient recited in the next-to-last paragraph on page 5 of the U.S. specification. The lower limit for the amount range of the active ingredient in claim 42 has been raised to 0.2 wt. %, which is supported by the amount range in example 5 on page 14 and

example 44 on page 19 of the U.S. specification. This is one of the smallest amounts of active ingredient used in all 51 examples presented in the applicants' specification so that claim 42 covers most of the examples. The amount range in claim 42 is also consistent with the USPTO policy regarding amended amount ranges during prosecution stated in M.P.E.P. § 2163.05 III.

The listed auxiliary agents in the second paragraph of step a have been selected so as to avoid including broad vague classes of compounds (dissolution promoters, stabilizers, UV absorbers) recited on page 7 which might include other compounds recited in the cited prior art (Stuckler) besides trigonelline, such as vitamin B6, pantothenic acid or betaines. Since the term "lanolin derivatives" might be considered indefinite, it has been replaced by "lanolin, lanolin alcohols and lanolin alkoxylate" (supported by examples 32 to 36 on page 17 of applicants' specification). Betaines, pantothenic acid and amphoteric surfactants have not been included in the listing of auxiliary agents because of their similarity to the active ingredients of Stuckler. The inclusion of VA/CA copolymer is supported by examples 9 to 11 on page 14 of applicants' specification. The term "Vaseline" is a trademark, which therefore should not be included in a patent claim.

The information regarding the amount limitations for the specific auxiliary ingredients from the third full paragraph on page 7 of the applicants' originally filed specification has been included in claim 42. However since the amphoteric surfactants have been excluded from the definition of the auxiliary agent, the amount range limitation for wetting agents and emulsifiers in claim 42 is stated as an amount range for the remaining surfactant classes, i.e. cationic surfactants, anionic surfactants and nonionic surfactants. Similarly the term "hair care agent" in the amount range limitations from page 7 that were introduced into claim 42 has been replaced by the specific hair care compounds that were actually recited as possible auxiliary agents in claim 42. Also the dissolution promoters and stabilizers have also been deleted from the amount range limitations since they are excluded because of the use of "consisting of" in the definition of the auxiliary agent.

Amended dependent claim 41 and new dependent claims 43 and 46 claim preferred embodiments of the method according to claim 42, but only recite additional limitations that further define the agent of step a of claim 42. Claims 43 and 44 include limitations that were already present in withdrawn dependent method claims 24 and 29 and thus are fully supported by the original disclosures. New dependent method claim 45 claims preferred forms of the agent and

is supported by the examples in the originally filed specification on page 14 and following. New dependent method claim 46 claims preferred pH adjusting compounds and is supported by the paragraph bridging pages 7 and 8 of the originally filed specification.

New independent method claims 47 and 48 contain the subject matter of the embodiments of the claimed method described in example 1 on pages 10 and 11 of the applicants' originally filed specification. They are based on the unexpected results in example 1 that shows that the rubbing resistances of tinted hair and permanently shaped are unexpectedly improved when trigonelline is included in the hair tinting composition and permanent wave composition respectively.

New independent method claim 49 claims the embodiment of the method described in example 3, which shows that the mechanical abrasion of hair color of hair dyed with a tinting composition is reduced when trigonelline hydrochloride is containing in the tinting composition.

New independent method claim 50 claims the embodiments of the method described in example 4, which shows that the hair

tensile strength can be unexpectedly increased by washing the hair with a shampoo containing trigonelline hydrochloride. New dependent method claim 51 claims the embodiments of the method of claim 50 limited to the preferred ingredients of the tested shampoo.

The amounts of active ingredient in the applied agents of independent method claims 47 to 50 are the amounts of the active ingredients in the agents disclosed in examples 1 to 4 and shown in figs. 1 to 3.

The prior pending dependent method claims 33 to 36 and 38 have been amended to change their dependencies from canceled claim 32 to the new independent method claim 42.

### **III. The Withdrawn Agent Claims**

The withdrawn claims for the agent itself have been amended so that they are in a condition for rejoinder under M.P.E.P. § 821.04 and allowance, provided that new independent method claim 42 is allowed.

Since this is the U.S. National Stage of PCT/EP 2005/001442,

the so-called "unity of invention" practice applies to the applicants' claims according to PCT article 13.1 and 13.2. Thus the criteria for rejoinder of the agent claims is that the independent agent claim contains the same agent composition limitations as step a of new independent method claim 42 and that new claim 42 is found to be allowable.

Thus the independent agent claim 19 has been amended so that it contains the same limitations as step a of claim 42.

The dependent agent claims have been corrected for minor informalities (claims 23 and 24). Dependent claim 25 for the cations has been amended by including the preferred cations from claim 26. Claim 26 has been amended to delete the cations recited in that claim and convert the claim into a claim for preferred forms of the agent. The subject matter of amended claim 26 is supported by the examples section of the applicants' specification.

Dependent claims 27 and 28 have been amended to include preferred amount ranges for the active ingredient. The reduced upper limits in claims 27 and 28 are based on the disclosures in the next-to-last paragraph on page 5 of applicants' specification. Example 6 on page 14 of the U.S. specification supports the lower

limit used in claim 28.

#### **IV. ARGUMENTS TO OVERCOME THE OBVIOUSNESS REJECTION**

Claims 32 to 38 were rejected as obvious under 35 U.S.C. § 103 (a) over U.S. Patent 5,133,958 (Stuckler) and U.S. Patent 6,861,077 (Cannell).

##### **A. The Applicants' Claimed Invention**

The subject matter of the applicants' new and amended claims and the claimed invention of the have been described in detail in the above sections I to III.

##### **B. The Content of the Prior Art**

The content of the two prior art references has been described in the REMARKS section of applicants' amendment filed on December 21, 2010. That description of the content of the prior art will not be repeated in detail here but is incorporated here by explicit reference thereto.

**C. Differences between the Claimed Invention and the Prior Art**

Stuckler discloses a method for hair care, for combating progressive hair loss and for stimulating fresh hair growth of human hair (column 1, lines 4 to 6). In contrast, applicants disclose and claim a method of repairing, strengthening and restructuring hair. This difference is reflected in the fact that the methods of application differ, since Stuckler advises oral administration (column 3, lines 16 to 23) or topical application of their compositions to the skin (column 3, lines 52 to 54), such as the scalp skin, whereas applicants advise direct application of their agent to the hair.

Stuckler discloses a generic agent composition comprising respective amounts of trigonelline and vitamin B6 in column 1, lines 27 to 30 and in claims 1, 2, 9 and 10 of US '958. The vitamin B6 (PLP, pyridoxal phosphate) is a **required** ingredient of the claimed agent according to U.S. '958 (see claims 1, 2 and the other independent claims of US'958). The agent of Stuckler may also include other adjuvant substances including nicotinic acid or acid amide and calcium pantothenate (claims 11 and 12) and amino acids (column 2 of US '958). In contrast, the applicants' claimed agent used in their claimed methods is defined with "consisting of"

wording, so that it does not contain any vitamin B6, which is required as an active ingredient in US '958.

**Furthermore, Stuckler does not disclose or suggest the effectiveness of trigonelline in repairing, restructuring or strengthening hair. Repairing, restructuring or strengthening hair is different from conventional hair care as explained on page 3, last five lines of text, to page 4, lines 1 to 8, of the written description in applicants' specification. Conventional hair care involves improving combability and/or luster of the hair and/or hair styling and/or increasing hair volume and thus is different from restructuring, repairing or strengthening hair. Also repairing, restructuring or strengthening hair is different from stimulating hair growth or arresting hair loss.**

**The effectiveness of trigonelline for the applicants' purposes is not disclosed or suggested in Stuckler.**

There is also no suggestion in Stuckler that the treatment with trigonelline and/or its salts will help to improve the resistance of the hair to damaging cosmetic treatments, such as oxidative dyeing, bleaching or permanent shaping (new claims 47 and 48).

Furthermore applicants' comparative experimental results on pages 8 to 14 of the specification have clearly established the effectiveness of their claimed method in improving abrasion resistance and also improving tear strength of the hair. No such comparative results are presented in Stuckler.

Furthermore independent claims 32 and 40 claim a method of treatment with critical acting time and temperature range limitations with subsequent rinsing. Stuckler does not teach or suggest either the acting time range or temperature range limitations of the independent claims. Stuckler does not teach the step of rinsing after the critical acting time range. Rinsing can be used because the increase in hair strength or abrasion resistance does not require that agent composition to remain on the hair, but is only due to the action of the agent during the critical acting time range.

In addition, in contrast to the statements on page 3 of the Office Action Stuckler does not disclose or suggest the salts of trigonelline (compounds of formula (II)) or in the case of the dependent claims the applicants' preferred active ingredients according to new dependent claims 39 and 41.

Cannell does not disclose trigonelline or compositions known

to contain trigonelline, although Cannell does disclose protecting hair from damage with any plant extract.

Cannell is also cited for teaching the conditions of leaving the extract on the hair at room temperature for a certain acting time and then rinsing according to the first paragraph on page 4 of the Office Action (see example 3 in column 8 of Cannell). However the action of any protective substance depends on its chemical composition so that the conditions of acting time and temperature used in a protective method and whether or not rinsing can occur depend on the chemical composition of the treatment agent. There is no relationship between the chemical composition of the treatment agent of example 3 of Cannell and the applicants' claimed compositions, because Cannell does not disclose a composition containing any trigonelline and/or salts of formula (II).

In fact, Cannell does not mention trigonelline and/or salts of formula (II) for any purpose at all in their treatment compositions. The similar compounds such as carnitine and betaine are not also not mentioned in Cannell as active ingredients for protecting hair. Thus since the applicants' ingredients are not disclosed in the plant extracts of Cannell the conditions of the methods of Cannell, such as acting times and temperature ranges, cannot be expected to be

helpful to one skilled in the art to determine or even suggest the corresponding conditions for a method of treating hair with e.g. the shampoos or lotions of Stuckler.

Of course if one coats the hair with a substance that forms a barrier coating, the diffusion of species, such as a protein, or the like would reasonably be at least reduced and thus the hair would be protected. In this sense the compositions of Cannell protect hair against damage.

Furthermore with respect to new claims 47 to 50, Stuckler or Cannell does not teach or suggest that their compositions can be used to treat hair in order to improve the rubbing resistance of tinted hair, the rubbing resistance of permanently shaped hair, the abrasion resistance of colors of dyed hair and the tear strength of damaged hair. Stuckler is completely silent regarding these particular properties of hair and methods to improve them. There is no suggestion of the features of claims 47 to 50 in Stuckler or Cannell.

In addition, the amount ranges of the active ingredient according to claims 49 to 50 do not overlap the amount ranges for

trigonelline in the specific aqueous cosmetic compositions claimed in claims 12 and 13 and disclosed in columns 3 and 4 of Stuckler. The compositions of claims 12 and 13 of Stuckler have from 0.3 to 0.7 wt. % of trigonelline, whereas the composition of claim 49 contains at least 5 wt. % and the agent of claim 50 contains at least 2.0 wt. % of the applicants' active ingredient, especially trigonelline.

#### **D. Reasons for Withdrawal of the Obviousness Rejection**

According to M.P.E.P. § 2144.05 a case of *prima facie* obviousness of a claimed composition comprising certain ingredients with certain amount ranges is established by a known composition disclosed in the prior art having the same ingredients in amount ranges that overlap, touch or are close to those of the claimed invention.

Certainly in the case of applicants' claims 49 and 50 the amount range for the applicants' active ingredient does not overlap, touch and is not close to that of disclosed hair treatment composition of claims 12 and 13 of Stuckler. Accordingly Stuckler cannot establish a case of *prima facie* obviousness of applicants' claims 49 and 50.

Cannel does not cure the deficiencies regarding the absence of a disclosure or suggestion of the amount ranges of claims 49 and 50.

Second with respect to new independent claim 42 and also claims 47 to 50, it is not obvious from Stuckler and Cannell that an agent with an active ingredient that did **not** include vitamin B6 (which is now excluded from applicants' claims) would be equally effective as an agent that includes vitamin B6 as required by Stuckler.

A rationale that it would be obvious to dispense with the vitamin B6 in the compositions of Stuckler and expect an effective method for treating the scalp to grow hair or to protect against hair loss is equivalent to an "obvious-to-try" rationale.

However this sort of "obvious-to-try" rationale is not a valid basis for an obviousness rejection of claim 42 or any other of the above claims (M.P.E.P. § 2143), because Stuckler provides no guidance or suggestion that would lead to employing an active ingredient that consists of only at least one of trigonelline and the compounds of formula II. When there are limitless possible

modifications of an active ingredient combination and the reference provides no guidance that would lead one to the applicants' choice, an obvious-to-try rationale is not valid. That is the situation in the case of Stuckler who suggests a large number of optional effective ingredients that will help promote hair growth and reduce hair loss including nicotinic acid or acid amide and pantothenic acid derivatives as well as amino acids and other vitamins (see column 2, lines 3 to 32).

The Federal Circuit Court of Appeals has considered the validity of obvious-to-try rationale after the *KSR* decision was made in *Takeda Chem. Indus. v. Alpha-pharm Pty., Ltd.*, 492 F.3<sup>rd</sup> 1350, 1356 (Fed. Cir. 2007). A similar case with the same conclusion is *Takeda : Eisai v. Dr. Reddy's Lab, and Teva Pharmaceuticals*, 2007-1397, 1398 (Fed. Cir. July 21, 2008). Quoting from their decision:

**"Obvious to Try is a valid rationale under KSR that establishes a case of prima facie obviousness when the inventor's solution to the prior art problem is selected from a "finite (meaning limited) number of identified (i.e. identified in the prior art), predictable (with a reasonable expectation of success given the level of technology in the particular art in question)"**

Accordingly in the absence of any specific guidance in Stuckler and in the face of an almost unlimited number of possible ways to modify the required combination of active ingredients of Stuckler it is

respectfully submitted that the combined prior art disclosures of Stuckler and Cannell do not establish a case of prima facie obviousness the applicants' new independent claim 42 and claims 47 to 50.

Predictability and an expectation of success of applicants' claimed method according to claim 42 based on the combined prior art disclosures is lacking in the case of the new more limited independent claims.

For the aforesaid reasons and because of the changes in the dependent claims, withdrawal of the rejection of amended dependent claims 33 to 36, 38 and 41 as obvious under 35 U.S.C. § 103 (a) over U.S. Patent 5,133,958 and U.S. Patent 6,861,077 is respectfully requested.

For the aforesaid reasons it is respectfully submitted that new method claims 42 to 51 should not be rejected as obvious under 35 U.S.C. § 103 (a) over U.S. Patent 5,133,958 and U.S. Patent 6,861,077.

Should the Examiner require or consider it advisable that the specification, claims and/or drawing be further amended or corrected in formal respects to put this case in condition for final allowance then it is requested that such amendments or corrections be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing the case to allowance, he or she is invited to telephone the undersigned at 1-631-549 4700.

In view of the foregoing, favorable allowance is respectfully solicited.

Respectfully submitted,  
/Michael J. Striker/

Michael J. Striker,  
Attorney for the Applicants  
Reg. No. 27,233